

**EXTRA STRENGTH STOOL SOFTENER LAXATIVE- docusate sodium capsule, liquid filled
Cardinal Health**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient (in each softgel)

Docusate Sodium 250 mg

Purpose

Stool softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Do not use

- if you are currently taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for more than 1 week, unless directed by a doctor

Ask a doctor before use if

you notice a sudden change in bowel habits that persists over a period of 2 weeks.

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

This package is intended for in-patient institutional use only.

Directions

- **adults and children 12 years of age and over:** take 1 softgel daily or as directed by a doctor
- **children under 12 years of age:** take as directed by a doctor

Other information

each softgel contains: sodium 15 mg

- store between 15°-30°C (59°-86°F)
- See window for lot number and expiration date

Inactive Ingredients

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified water, sorbitol special

Questions or comments?

1-800-645-2158

Extra Strength Stool Softener Laxative
Docusate Sodium USP, 250 mg

SOFTGEL CAPSULES

Distributed by: Rugby Laboratories

31778 Enterprise Drive

Livonia, MI 48150

www.rugbylaboratories.com

Rugby is trademark of its respective owner.

Repackaged by: Cardinal Health

Zanesville, OH 43701

LUC4600029-10114

LUC4600029-20114

Principal Display Panel

Stool Softener

(docusate sodium USP)

250 mg



Principal Display Panel

Stool Softener
 (docusate sodium USP)
 250 mg
 100 Softgel Capsules

NDC 55154-6812-4
 Stool Softener
 (docusate sodium USP)
 250 mg
 100 Softgel Capsules

NDC 55154-6812-4
 Stool Softener
 (docusate sodium USP)
 250 mg
 100 Softgel Capsules

EXTRA STRENGTH LAXATIVE
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Docusate Sodium 250 mg	Stool Softener

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Warnings
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Ask a doctor before use if you notice a sudden change in bowel habits that persists over a period of 2 weeks.

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Drug Facts (continued)

Warnings (continued)

Stop use and ask a doctor if • you have rectal bleeding
 • you fail to have a bowel movement after use
 These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. This package is intended for in-patient institutional use only. This package is not child resistant. In case of overdose, get medical help or contact a Poison Control Center right away.


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 • **children under 12 years of age:** take as directed by a doctor

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 Repackaged by: Cardinal Health
 Zanesville, OH 43701 LUC4600029-20114

Principal Display Panel

Stool Softener
 Laxative

Docusate Sodium USP, 250 mg

10 SOFTGEL CAPSULES



NDC 55154-6812-0

W93

**STOOL SOFTENER
LAXATIVE**

Docusate Sodium USP, 250 mg

10 SOFTGEL CAPSULES

EXTRA STRENGTH

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(in each softgel)

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STORAGE: store between 15 - 30 C (59 - 86 F)

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- for more than 1 week, unless directed by a doctor

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Zanesville, OH 43701

L46000290114

LOT #: XXXX



EXP. DATE: 12/34



EXTRA STRENGTH STOOL SOFTENER LAXATIVE

docusate sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-6812(NDC:0536-3757)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	orange (orange)	Score	no score
Shape	OVAL (OVAL)	Size	20mm
Flavor		Imprint Code	P20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-6812-4	100 in 1 CARTON		
1	NDC:55154-6812-6	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:55154-6812-0	10 in 1 BAG		
2		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/29/2012	

Labeler - Cardinal Health (188557102)**Establishment**

Name	Address	ID/FEI	Business Operations
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Cardinal Health		188557102	REPACK(55154-6812)
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Revised: 9/2014

Cardinal Health